

**IN THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

MDL Docket No. 2738

This Document Relates To:
Bondurant v. Johnson & Johnson
 No. 3:19-cv-14366-MAS-RLS

Gallardo v. Johnson & Johnson
No. 3:18-cv-10840-MAS-RLS

Judkins v. Johnson & Johnson
No. 3:19-cv-12430-MAS-RLS

**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT,
LLC'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO
EXCLUDE THE SPECIFIC CAUSATION OPINIONS OFFERED BY DR.
JUDITH WOLF**

FAEGRE DRINKER BIDDLE &
REATH LLP
*A Delaware Limited Liability
Partnership*
600 Campus Drive
Florham Park, New Jersey 07932
(973) 549-7000

SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001

212-735-3000

*Attorneys for Defendants Johnson &
Johnson and LLT Management, LLC*

TABLE OF CONTENTS

	<u>Page</u>
BACKGROUND	3
ARGUMENT	8
I. DR. WOLF’S SPECIFIC CAUSATION OPINIONS AS TO MS. BONDURANT MUST BE EXCLUDED BECAUSE THERE IS NO ASSOCIATION BETWEEN TALC EXPOSURE AND CLEAR CELL CANCER.	8
II. DR. WOLF’S OPINIONS ARE NOT BASED ON A DIFFERENTIAL DIAGNOSIS.	12
III. DR. WOLF DID NOT RELIABLY “RULE IN” TALC AS A CAUSE OF ANY PLAINTIFF’S CANCER OR “RULE OUT” OTHER POTENTIAL CAUSES.	14
A. Dr. Wolf Failed To Reliably “Rule In” Talc As A Possible Cause Of Any Plaintiff’s Ovarian Cancer.	14
B. Dr. Wolf Failed to Reliably “Rule Out” Other Potential Causes Of Any Plaintiff’s Cancer.	16
1. Dr. Wolf Failed To Reliably “Rule Out” Other Potential Causes Of Ms. Bondurant’s Ovarian Cancer.	19
2. Dr. Wolf Failed To Reliably “Rule Out” Other Potential Causes Of Ms. Judkins’ Ovarian Cancer.	23
3. Dr. Wolf Failed To Reliably “Rule Out” Other Potential Causes Of Ms. Gallardo’s Ovarian Cancer.	26
C. Dr. Godleski’s Findings Provide No Support For Dr. Wolf’s Specific Causation Opinions.	27
CONCLUSION	28

TABLE OF AUTHORITIES

Page(s)

CASES

<i>In re Accutane Products Liability</i> , No. 04-2523, 2009 WL 2496444 (M.D. Fla. Aug. 11, 2009)	28
<i>In re Avandia Marketing, Sales Practices & Products Liability Litigation</i> , MDL No. 1871, 2011 WL 135017 (E.D. Pa. Jan. 13, 2011).....	13
<i>Bland v. Verizon Wireless (VAW) L.L.C.</i> , 538 F.3d 893 (8th Cir. 2008)	24
<i>Cano v. Everest Minerals Corp.</i> , 362 F. Supp. 2d 814 (W.D. Tex. 2005)	18
<i>Chapman v. Procter & Gamble Distrib., LLC</i> , 766 F.3d 1296 (11th Cir. 2014)	24
<i>Feit v. Great West Life & Annuity Insurance Co.</i> , 271 F. App'x 246 (3d Cir. 2008).....	16
<i>Fireman's Fund Insurance Co. v. Canon U.S.A., Inc.</i> , 394 F.3d 1054 (8th Cir. 2005)	16
<i>Guerrero v. BP Exploration & Production Inc.</i> , No. 20-0263, 2024 WL 1244796 (M.D. Fla. Mar. 20, 2024).....	17
<i>Guinn v. AstraZeneca Pharmaceuticals LP</i> , 602 F.3d 1245 (11th Cir. 2010)	18, 19, 23
<i>Hall v. Conoco Inc.</i> , 886 F.3d 1308 (10th Cir. 2018)	25
<i>Kilpatrick v. Breg, Inc.</i> , 613 F.3d 1329 (11th Cir. 2010)	25

<i>In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Products Liability Litigation,</i> 185 F. Supp. 3d 786 (D.S.C. 2016)	17
<i>In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Products Liability Litigation,</i> 892 F.3d 624 (4th Cir. 2018)	17
<i>Magistrini v. One Hour Martinizing Dry Cleaning,</i> 180 F. Supp. 2d 584 (D.N.J. 2002).....	11
<i>Milward v. Rust-Oleum Corp.,</i> 820 F.3d 469 (1st Cir. 2016).....	25, 27
<i>In re Mirena Ius Levonorgestrel-Related Products Liability Litigation (No. II),</i> 341 F. Supp. 3d 213 (S.D.N.Y. 2018)	28
<i>Pritchard v. Dow Agro Sciences,</i> 430 F. App'x. 102 (3d Cir. 2011)	16
<i>Pugh v. Community Health Systems, Inc.,</i> No. 20-00630, 2023 WL 3361166 (E.D. Pa. May 10, 2023)	13
<i>Rutigliano v. Valley Business Forms,</i> 929 F. Supp. 779 (D.N.J. 1996).....	16
<i>Soldo v. Sandoz Pharmaceuticals Corp.,</i> 244 F. Supp. 2d 434 (W.D. Pa. 2003)	11, 17, 19
<i>Storey v. Transformhealthrx, Inc.,</i> No. 415-149, 2024 WL 695410 (S.D. Ga. Feb. 20, 2024)	23
<i>Tamraz v. Lincoln Electric Co.,</i> 620 F.3d 665 (6th Cir. 2010)	24
<i>In re Zantac (Ranitidine) Products Liability Litigation,</i> 644 F. Supp. 3d 1075 (S.D. Fla. 2022).....	10

RULE

Fed. R. Evid. 702	8
-------------------------	---

OTHER AUTHORITIES

Barnard, <i>Endometriosis Typology and Ovarian Cancer Risk</i> , JAMA (2024).....	6, 20
Berge, <i>Genital Use of Talc and Risk of Ovarian Cancer: A Meta-analysis</i> , 27(3) Eur. J. Cancer Prev. 248 (2018).....	9, 12
Cramer, <i>The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States</i> , 27(3) Epidemiology 334 (2016).....	12
Cramer, <i>Presence of Talc in Pelvic Lymph Nodes of a Woman With Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc</i> , 110(2) Obstet. & Gynecol. 498 (2007)	28
Gabriel, <i>Douching, Talc Use, and Risk for Ovarian Cancer and Conditions Related to Genital Tract Inflammation</i> , 28(11) Cancer Epidemiol. Biomarkers Prev. 1835 (2019).....	9
Heller, <i>The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden</i> , 174(5) Am. J. Obstet. Gynecol. 1507 (1996).....	28
Liu, <i>Menopausal Hormone Replacement Therapy and the Risk of Ovarian Cancer: A Meta-Analysis</i> , 10(801) Front. Endocrinol. 1 (2019)	26
Noli, <i>Long Term Survival of Ovarian Endometriosis Associated Clear Cell and Endometrioid Ovarian Cancers</i> , 23(2) Int’l J. Gynecol. Cancer 244 (2013).....	6
Penninkilampi & Eslick, <i>Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis</i> , 29(1) Epidemiology 41 (2018)	9
Saavalainen, <i>Risk of Gynecologic Cancer According to the Type of Endometriosis</i> , 131(6) Obstet. & Gynecol. 1095 (2018)	6, 20

Taher, <i>Critical Review of the Association Between Perineal Use of Talc Powder and Risk of Ovarian Cancer</i> , 90 <i>Reproductive Toxicology</i> 88 (2019).....	9
Wentzensen & O’Brien, <i>Talc, Body Powder, and Ovarian Cancer: A Summary of the Epidemiologic Evidence</i> 163 <i>Gynecol. Oncol.</i> 199 (2021).....	8

Dr. Judith Wolf seeks to testify that talc use was a substantial contributing cause of the different subtypes of ovarian cancer experienced by three of the bellwether plaintiffs: Linda Bondurant, Carter Judkins, and Anna Gallardo. Dr. Wolf's specific causation opinions should be excluded for several reasons.¹

First, Dr. Wolf's opinion regarding Ms. Bondurant is unreliable at the threshold because the science does not even establish an association between talc exposure and clear cell carcinoma, the subtype of ovarian cancer with which she was diagnosed, let alone causation. In asserting that talc exposure caused Ms. Bondurant's clear cell carcinoma, Dr. Wolf relies on scientific literature addressing whether an association exists between talc use and *all ovarian cancers*. But this literature is heavily focused on high-grade serous ovarian cancer, the most common subtype of the disease, and does not demonstrate an association with respect to clear cell carcinoma.

Second, Dr. Wolf's specific causation opinions with respect to all three plaintiffs are inadmissible because she did not apply any real methodology in determining that talc use substantially contributed to each plaintiff's ovarian cancer. While Dr. Wolf purports to have employed a "differential diagnosis" in reaching her specific causation opinions, in truth she used no methodology at all.

¹ Judge Wolfson's *Daubert* ruling only addressed general causation issues and therefore did not address the arguments in this motion.

Rather, her bottom-line opinion is that if a woman used talc and developed ovarian cancer, her talc use was a cause of her cancer. For example, Dr. Wolf testified that Ms. Gallardo's claim of "talcum powder use" is enough for her to opine "that her cancer was caused by her use of talcum powder."² Simply assuming that any time a woman exposed to talc develops ovarian cancer, the talc must have played a causal role is not a reliable methodology.

Third, to the extent Dr. Wolf's process can be characterized as a differential diagnosis, her opinions are still inadmissible because she did not reliably "rule in" talc as a potential cause of each woman's cancer; nor did she "rule out" other potential (and in some cases, far more likely) causes of their cancers, including the possibility that, like most cancers, their diseases are idiopathic (i.e., have no known origin).

Dr. Wolf's attempt to rule in talc as a cause of any plaintiff's ovarian cancer is unreliable because, as explained in Defendants' General Causation *Daubert* brief, there is no reliable scientific support for the assertion that talc exposure can **ever** cause ovarian cancer. In addition, Dr. Wolf failed to adequately consider that: (1) Ms. Bondurant had a tubal ligation decades before she developed cancer, cutting off the pathway by which Dr. Wolf believes talc could have reached her

² (Dep. of Judith Wolf ("9/13/21 Wolf Dep.") 407:3-10, Sept. 13, 2021 (Ex. 1 to Decl. of Jessica Davidson ("Davidson Decl.")).)

ovaries; and (2) Ms. Gallardo was diagnosed 25 years after her alleged last talc use, which is inconsistent with Dr. Wolf's testimony regarding the latency period for her ovarian cancer.

In addition, Dr. Wolf failed to reliably "rule out" the many other potential causes of the various plaintiffs' cancers. Most shockingly, Dr. Wolf ignores Ms. Bondurant's endometriosis, even though studies have shown that women with endometriosis have up to a **900 percent increased risk** of developing clear cell ovarian cancer. Instead of ruling out this and other risk factors for the three plaintiffs, Dr. Wolf suggests that all risk factors somehow work together to contribute to a woman's ovarian cancer. But Dr. Wolf does not cite any science suggesting that is how ovarian cancers develop—and no such science exists.

Finally, to the extent Dr. Wolf attempts to rely on Dr. Godleski's findings of particles consistent with talc in the pelvic tissue of two of the three plaintiffs at whose trials she seeks to testify, those findings are unreliable—and also irrelevant—and therefore cannot support Dr. Wolf's specific causation opinions.

BACKGROUND

Dr. Wolf is a gynecologic oncologist who seeks to testify that three of the bellwether plaintiffs' alleged "regular use of talcum powder products . . . is a

substantial contributing cause” of their cancers.³ Dr. Wolf asserts that these specific causation opinions are based on what Dr. Wolf claims is a “differential diagnosis” methodology.⁴

As part of her differential diagnosis, Dr. Wolf claims to have “ruled in” talc use as a potential cause of each plaintiff’s cancer based on their reports of talc use.⁵ More than that, Dr. Wolf takes the position that each plaintiff’s claim of “talcum powder use” is enough for her to opine “that her cancer was caused by her use of talcum powder.”⁶ Dr. Wolf acknowledged, however, that professional organizations, including the Society of Gynecologic Oncologists, National Cancer Institute, National Ovarian Cancer Coalition, and the Centers for Disease Control have *not* identified talc as a risk factor for ovarian cancer.⁷ Further, Dr. Wolf admitted that “[j]ust because a woman has a risk factor for ovarian cancer, that doesn’t mean that that risk factor is going to cause the disease.”⁸ Indeed, she

³ (2d Am. Rep. of Judith Wolf Re: Linda Bondurant (“Bondurant Rep.”) at 24-25, May 28, 2024 (Ex. 2 to Davidson Decl.); 2d Am. Rep. of Judith Wolf Re: Carter Judkins (“Judkins Rep.”) at 23-24, May 28, 2024 (Ex. 3 to Davidson Decl.); 2d Am. Rep. of Judith Wolf Re: Anna Gallardo (“Gallardo Rep.”) at 23-24, May 28, 2024 (Ex. 4 to Davidson Decl.).)

⁴ (Dep. of Judith Wolf (“9/14/21 Wolf Dep.”) 511:23-512:2, Sept. 14, 2021 (Ex. 5 to Davidson Decl.).)

⁵ (Bondurant Rep. at 24; Judkins Rep. at 23; Gallardo Rep. at 23.)

⁶ (9/13/21 Wolf Dep. 407:3-10; 9/14/21 Wolf Dep. 576:9-21.)

⁷ (9/13/21 Wolf Dep. 251:18-253:18.)

⁸ (*Id.* 270:3-10.)

concedes that “there are many women who have used talc and have not gotten ovarian cancer.”⁹ Thus, Dr. Wolf “can’t say for sure in any individual case [] that talc caused ovarian cancer.”¹⁰

Dr. Wolf also concedes that each of the plaintiffs at issue has a number of risk factors unrelated to talc use that could have contributed to her ovarian cancer.¹¹ Specifically, Dr. Wolf notes that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED].¹³ Dr. Wolf has conceded that both endometriosis and such a family history of gynecological cancer are “significant” risk factors for ovarian cancer.¹⁴

The scientific literature has identified a strong association between endometriosis and clear cell ovarian cancer, with one population-based study

⁹ (*Id.* 277:6-15.)

¹⁰ (*Id.* 269:9-16.)

¹¹ (*See* Bondurant Rep. at 24; Judkins Rep. at 24; Gallardo Rep. at 24.)

¹² (Bondurant Rep. at 23; 9/14/21 Wolf Dep. 438:2-3, 439:19-20.)

¹³ (9/14/21 Wolf Dep. 464:2-12.)

¹⁴ (Bondurant Rep. at 23; *see also id.* at 25 [REDACTED]
[REDACTED]); 9/14/21 Wolf Dep. 462:6-7 (“Endometriosis is a risk factor for ovarian cancer”).) Dr. Wolf also acknowledged that “[a]dvancing age can always be a risk factor.” (*Id.* 577:14-25.)

reporting an odds ratio as high as 10.1 (CI = 5.50-16.9).¹⁵ In other words, endometriosis, on its own, has been found to be associated with a **900%** increased risk of clear cell carcinoma of the ovary. These results were reconfirmed in a study published just this month, which reported an unadjusted odds ratio of 10.90 (CI = 6.02-19.74) and a multivariable-adjusted odds ratio of 11.15 (CI = 6.19-20.10) between endometriosis and clear cell ovarian cancer relative to women without endometriosis.¹⁶ In addition, Dr. Wolf concedes that Ms. Bondurant's [REDACTED] **doubles** her risk of clear cell ovarian cancer.¹⁷

Dr. Wolf testified that she did not need to “rule out” Ms. Bondurant's [REDACTED] because she did not “have a confirmation” of the reports of endometriosis in Ms. Bondurant's medical records. This position reflects a result-oriented approach, particularly since Dr. Wolf **did** take Ms. Bondurant at her word that she used talcum powder without any further confirmatory evidence.¹⁸

¹⁵ Saavalainen, *Risk of Gynecologic Cancer According to the Type of Endometriosis*, 131(6) *Obstet. & Gynecol.* 1095, 1095 (2018) (“Saavalainen 2018”) (Ex. 6 to Davidson Decl.); see also Noli, *Long Term Survival of Ovarian Endometriosis Associated Clear Cell and Endometrioid Ovarian Cancers*, 23(2) *Int'l J. Gynecol. Cancer* 244 (2013) (“Noli 2013”) (Ex. 7 to Davidson Decl.).

¹⁶ Barnard, *Endometriosis Typology and Ovarian Cancer Risk*, *JAMA* (2024), at E3 tbl. 2 (“Barnard 2024”) (Ex. 8 to Davidson Decl.).

¹⁷ (Bondurant Rep. at 25 [REDACTED] [REDACTED]).)

¹⁸ (9/14/21 Wolf Dep. 463:22-464:12.)

As to the other two bellwether plaintiffs, Dr. Wolf concedes that Ms. Judkins, who was diagnosed with high grade serous ovarian cancer, has a [REDACTED] [REDACTED] that increased her cancer risk.¹⁹ And Dr. Wolf likewise concedes that Ms. Gallardo, who was diagnosed with endometrioid ovarian cancer, underwent [REDACTED]—an additional risk factor that could have caused her ovarian cancer.²⁰

Rather than “rule out” any of these plaintiffs’ various risk factors for ovarian cancer, Dr. Wolf claims that ovarian cancer is “multifactorial” and that “all of [the factors] could be a cause of [the patient’s] cancer.”²¹ In other words, Dr. Wolf asserts that plaintiffs’ talc use *and* all of their other risk factors together were the “cause” of their ovarian cancer.²² Unlike Dr. Clarke-Pearson, Dr. Wolf admits that she cannot “assess percentage of cause from different individual risk factors”²³ or “apportion out or say to what percent any one risk factor may have been a cause”²⁴ of each plaintiff’s disease.

¹⁹ (See *id.* 579:2-7 (conceding Ms. Judkins’ paternal great aunt’s history of cancer was a risk factor).)

²⁰ (Gallardo Rep. at 24.)

²¹ (9/14/21 Wolf Dep. 523:17-19.)

²² (9/13/21 Wolf Dep. 324:8-11; 325:18-24; 9/14/21 Wolf Dep. 533:11-19.)

²³ (9/14/21 Wolf Dep. 527:18-21.)

²⁴ (9/13/21 Wolf Dep. 398:14-19.)

ARGUMENT

The standard for the admissibility of expert evidence under Amended Fed. R. Evid. 702 is set forth in Defendants' General Causation *Daubert* brief and incorporated herein. In addition, the standard for the admissibility of expert opinions related to specific causation that are based on a "differential diagnosis" method is set forth in defendants' briefing in support of their Motion to Exclude the Opinions of Dr. Clarke-Pearson, also incorporated herein. Dr. Wolf's specific causation opinions do not satisfy these standards for a variety of reasons.

I. DR. WOLF'S SPECIFIC CAUSATION OPINIONS AS TO MS. BONDURANT MUST BE EXCLUDED BECAUSE THERE IS NO ASSOCIATION BETWEEN TALC EXPOSURE AND CLEAR CELL CANCER.

Dr. Wolf's opinions as to Ms. Bondurant must be excluded at the threshold because there is no evidence that talc use is even associated with Ms. Bondurant's specific subtype of ovarian cancer—clear cell carcinoma—let alone evidence of causation.

As set forth in defendants' General Causation *Daubert* brief, ovarian cancer is not a single disease; rather, there are many different subtypes of ovarian cancer.²⁵ The studies that have reported on relative risks by ovarian cancer subtype

²⁵ (See Defs.' Mem. in Supp. of Mot. to Exclude Pls.' Experts' General Causation Ops. at 15-16, 72-74.) Wentzensen & O'Brien, *Talc, Body Powder, and Ovarian Cancer: A Summary of the Epidemiologic Evidence* 163 Gynecol. Oncol. (cont'd)

have overwhelmingly shown *no* increased risk of clear cell carcinoma. For example, several meta-analyses (on which Dr. Wolf relies heavily for her general causation opinion) have reported on the association between talc use and clear cell carcinoma, with results that are all essentially equal to a null association or below it.²⁶ In addition, a recent case-control study authored by a plaintiffs' expert in talcum powder litigation likewise found no statistically significant odds ratio for clear cell carcinoma (OR: 1.08; 95% CI: 0.66-1.78).²⁷ Indeed, of all the epidemiological studies that have analyzed the purported association between talc

199, 202 (2021) (“Wentzensen & O’Brien 2021”) (Ex. 9 to Davidson Decl.) (“Ovarian cancer is characterized by profound heterogeneity that can be observed in site of origin, genetic susceptibility, somatic mutations, molecular pathways, risk factor associations and morphologic differences.”).

²⁶ See Berge, *Genital Use of Talc and Risk of Ovarian Cancer: A Meta-analysis*, 27(3) Eur. J. Cancer Prev. 248, 251 (2018) (“Berge 2018”) (Ex. 10 to Davidson Decl.) (“No significant associations were detected for . . . clear cell (RR: 0.98; 95% CI: 0.72–1.23) carcinomas.”); Taher, *Critical Review of the Association Between Perineal Use of Talc Powder and Risk of Ovarian Cancer*, 90 Reproductive Toxicology 88, 93 (2019) (“Taher 2019”) (Ex. 11 to Davidson Decl.) (OR: 0.63; 95% CI: 0.15-2.65 for “clear cell”); Penninkilampi & Eslick, *Perineal Talc Use and Ovarian Cancer: A Systematic Review and Meta-Analysis*, 29(1) Epidemiology 41, 44 (2018) (“Penninkilampi 2018”) (Ex. 12 to Davidson Decl.) (OR: 1.02; 95% CI: 0.75-1.39 for clear cell carcinoma; “[w]e found an increased risk of serous and endometrioid, but not mucinous or clear cell subtypes”).

²⁷ Gabriel, *Douching, Talc Use, and Risk for Ovarian Cancer and Conditions Related to Genital Tract Inflammation*, 28(11) Cancer Epidemiol. Biomarkers Prev. 1835, 1841 tbl. 4 (2019) (“Gabriel 2019”) (Ex. 13 to Davidson Decl.).

use and clear cell carcinoma of the ovary, only *one*, Terry 2013, shows a statistically significant increased risk.²⁸

<u>Author</u>	<u>Year</u>	<u>Study Type</u>	<u>Clear Cell O.R. (C.I)</u>
Cramer ²⁰⁴	1999	Meta-Analysis	1.04 (0.67-1.61)*
Wong ²⁰⁵	1999	Case Control	1.6 (0.6-4.3)
Mills ²⁰⁶	2004	Case Control	0.63 (0.15-2.64)
Merritt ²⁰⁷	2008	Case Control	1.08 (0.68-1.72)
Rosenblatt ²⁰⁸	2011	Case Control	1.53 (0.91-2.57)*
Terry ²⁰⁹	2013	Pooled	1.24 (1.01-1.52)
Cramer ²¹⁰	2016	Case Control	1.01 (0.65-1.57)
Berge ²¹¹	2018	Meta-Analysis	0.98 (0.72-1.23)
Penninkilampi ²¹²	2018	Meta-Analysis	1.02 (0.75-1.39)
Taher ²¹³	2019	Meta-Analysis	0.63 (0.15-2.65)
O'Brien ²¹⁴	2020	Pooled	1.17 (0.73-1.89)

Dr. Wolf nonetheless claims that clear cell carcinoma has been “associated” with talcum powder use.²⁹ But, as Dr. Wolf admits, this opinion is based primarily on studies that “lumped clear-cell with endometrioid and other subtypes,” and is contrary to the many studies described above that address clear cell carcinoma in particular and found no association.³⁰ Such “commingl[ing] [of] data . . . departs from conventional science” and renders expert testimony inadmissible. *See In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1233 (S.D. Fla.

²⁸ (Rep. of Michael A. Finan Re: Linda Bondurant at 66, May 28, 2024 (Ex. 14 to Davidson Decl.).) Cramer 1999 and Rosenblatt 2011 include combined odds ratios for clear cell and endometrioid carcinoma.

²⁹ (Bondurant Rep. at 24.)

³⁰ (9/14/21 Wolf Dep. 478:7-10.)

2022) (criticizing and excluding plaintiffs’ expert for relying on a study “where stomach cancer was commingled with esophageal cancer” for her “final analysis for stomach cancer”); *see also Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 564 (W.D. Pa. 2003) (excluding expert testimony that a drug “causes strokes different from the kind that plaintiff experienced” because such testimony did not fit the facts of the case); *cf. Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 603 (D.N.J. 2002) (excluding causation expert who did not provide “good grounds” for his testimony that “all lymphohematopoietic cancers can be treated together for etiological purposes”), *aff’d*, 68 F. App’x 356 (3d Cir. 2003).

Even if Dr. Wolf could reliably opine that talc use is a cause of clear cell carcinoma based on the outlier Terry 2013 study, which she claims demonstrates a “statistically significant increased risk for clear-cell ovarian cancer,”³¹ the results of that study have been called into question by subsequent research. Terry 2013 utilized data from eight datasets, only two of which demonstrated a statistically significant association. The data from one of the two sets that is reported as showing an association between talc use and clear cell carcinoma was later analyzed in another study, Cramer 2016, which found ***no increased risk*** of clear

³¹ (*Id.* 478:15-19.)

cell carcinoma in talc users.³² In addition, the even more recent Berge 2018 study, which also included the underlying data analyzed in Terry 2013, showed no association between talc use and clear cell carcinoma.³³ Dr. Wolf never addressed or explored notable discrepancies in the Terry study's underlying data, including the fact that Terry 2013 reported over 160 more cases of clear cell cancer in the data it studied than did Cramer 2016, which was based on the exact same data.³⁴

In short, Dr. Wolf's opinion that there is a causal link between talc use and clear cell carcinoma is directly refuted by the medical literature. For this reason alone, Dr. Wolf's specific causation opinion as to Ms. Bondurant should be excluded from trial.

II. DR. WOLF'S OPINIONS ARE NOT BASED ON A DIFFERENTIAL DIAGNOSIS.

Dr. Wolf's assertion that talc is the cause of the different subtypes of ovarian cancer experienced by Ms. Bondurant, Ms. Judkins and Ms. Gallardo is inherently unreliable because it is not the result of any methodology, but is instead based on

³² Cramer, *The Association Between Talc Use and Ovarian Cancer: A Retrospective Case-Control Study in Two US States*, 27(3) *Epidemiology* 334 (2016) ("Cramer 2016") (Ex. 15 to Davidson Decl.).

³³ See Berge 2018 at 250 (the authors "used the results reported in the meta-analysis by Terry *et al.* (2013) for six of the original eight studies" and used "more extensive results reported in subsequent publications" for the other two studies).

³⁴ (9/14/21 Wolf Dep. 480:1-7.)

the speculative assumption that talcum powder is *always* a cause of a woman's ovarian cancer if she reports using the product.³⁵

According to Dr. Wolf, plaintiffs' allegations that they "used talcum powder" are enough for her to conclude that talcum powder "was a cause of [their] cancer[s]."³⁶ Dr. Wolf further believes that talc use is a risk factor for ovarian cancer because it has been "associated" with ovarian cancer in the scientific literature.³⁷ But courts have repeatedly rejected specific causation opinions based solely on a finding of an association between exposure and injury in the scientific literature. *See, e.g., Pugh v. Cmty. Health Sys., Inc.*, No. 20-00630, 2023 WL 3361166, at *14 (E.D. Pa. May 10, 2023) ("Without additional support and explanation, Dr. Mulkey's specific causation opinions based on her finding of a mere association between factors amount to an unreliable 'speculative leap.'") (citation omitted); *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 1871, 2011 WL 135017, at *4-5 (E.D. Pa. Jan. 13, 2011) (excluding specific causation opinion that was "largely based upon studies showing an increased risk of cardiovascular mortality and myocardial infarctions for patients taking Avandia"

³⁵ (*Id.* 523:5-8 ("If . . . there was adequate evidence that she had talc use, I would consider that a cause of her cancer.").)

³⁶ (*Id.* 407:3-10, 576:9-21; *see also id.* 518:20-519:7 ("if a [woman] has [a] risk factor and she gets ovarian cancer," she can "generally attribute that risk factor as . . . a cause of her cancer").)

³⁷ (Bondurant Rep. at 24; Gallardo Rep. at 23; Judkins Rep. at 23.)

because it was based on “an improper inferential leap from general causation to specific causation . . . without any evidence to show that Avandia caused or even contributed to” the plaintiff’s alleged injury).

Similarly here, Dr. Wolf’s failure to employ a reliable methodology, instead assuming that any risk factor is a “specific cause” of a plaintiff’s injury, renders her specific causation opinions unreliable and inadmissible.

III. DR. WOLF DID NOT RELIABLY “RULE IN” TALC AS A CAUSE OF ANY PLAINTIFF’S CANCER OR “RULE OUT” OTHER POTENTIAL CAUSES.

Even if Dr. Wolf’s opinions could be characterized as the product of a “differential diagnosis,” she did not reliably apply that methodology with respect to any of the plaintiffs at issue.

A. Dr. Wolf Failed To Reliably “Rule In” Talc As A Possible Cause Of Any Plaintiff’s Ovarian Cancer.

Dr. Wolf’s so-called “ruling in” of talc as a possible cause of each plaintiff’s ovarian cancer is unreliable and should be excluded.

For one thing, as explained in Defendants’ General Causation *Daubert* brief (incorporated herein), there is no reliable scientific support for the assertion that talc exposure can *ever* cause ovarian cancer. In addition, Dr. Wolf’s attempt to “rule in” talc also fails to account for each plaintiff’s particular medical history. Critically, Dr. Wolf ignores the fact that Ms. Bondurant underwent [REDACTED] decades before her cancer occurred, which, under Dr. Wolf’s own theory of

causation, would have closed off any purported route by which “the talcum powder could get to her ovaries.”³⁸ Specifically, Ms. Bondurant underwent [REDACTED] in 1987, approximately *31 years before* her ovarian cancer diagnosis.³⁹ According to Dr. Wolf, a latency period of 15 to 20 years following talc use is reasonable for ovarian cancer.⁴⁰ Thus, based on Dr. Wolf’s own opinions, the route by which talc could have reached Ms. Bondurant’s ovary and caused cancer was closed long before the supposed latency period for talc and ovarian cancer.

Dr. Wolf’s opinions with respect to Ms. Gallardo suffer from a similar flaw. Ms. Gallardo claims to have used talcum powder from 1968 to 1988 and testified that she has not used any talc since then.⁴¹ Because Ms. Gallardo was diagnosed with ovarian cancer in 2013—25 years after the last talc use which could have affected her pursuant to Dr. Wolf’s theory of exposure—the latency period with respect to Ms. Gallardo was half a decade longer than the 15-to-20-year latency period Dr. Wolf agreed was typical.⁴²

³⁸ (9/14/21 Wolf Dep. 634:5-7.)

³⁹ (*Id.* 549:20-21.)

⁴⁰ (*Id.* 571:2-6.)

⁴¹ (Dep. of Anna Gallardo (“1/12/21 Gallardo Dep.”) 38:6-13, Jan. 12, 2021 (Ex. 16 to Davidson Decl.).)

⁴² (*See* 9/14/21 Wolf Dep. 571:2-6.)

Notably, Dr. Wolf offers no explanation for these internal inconsistencies, which “seriously undermines the reliability of” her opinions. *Fireman’s Fund Ins. Co. v. Canon U.S.A., Inc.*, 394 F.3d 1054, 1059 (8th Cir. 2005). For this reason, too, Dr. Wolf did not reliably “rule in” talc exposure as a cause of any of the plaintiffs’ cancers.

B. Dr. Wolf Failed to Reliably “Rule Out” Other Potential Causes Of Any Plaintiff’s Cancer.

Dr. Wolf’s specific causation opinions are also inadmissible because she failed to reliably “rule out” other potential causes of each plaintiff’s cancer. “Courts have insisted time and time again that an expert may not give opinion testimony to a jury regarding specific causation if the expert has not engaged in . . . the process of eliminating other possible diagnoses.” *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 786 (D.N.J. 1996), *aff’d sub nom. Valley Bus. Forms v. Graphic Fine Color, Inc.*, 118 F.3d 1577 (3d Cir. 1997); *see also, e.g., Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App’x 246, 254 (3d Cir. 2008) (affirming exclusion of specific causation testimony as unreliable, in part because expert “failed to rule out the possibility” of another cause of decedent’s death); *Pritchard v. Dow Agro Scis.*, 430 F. App’x. 102, 105 (3d Cir. 2011) (affirming exclusion of specific causation expert where expert “failed to adequately address possible alternative causes of [plaintiff]’s cancer”). Thus, “[e]ven if plaintiff’s expert[]” can establish a link between exposure to a certain product and plaintiff’s alleged

injury, “failure to reliably ‘rule out’ possible causes of plaintiff’s” injury would “render[] their methodology unreliable.” *Soldo*, 244 F. Supp. 2d at 532.

Dr. Wolf does not even try to rule out plaintiffs’ significant risk factors, but instead insists that each of them—along with talc—are “causes” of the plaintiffs’ ovarian cancers.⁴³ It is well recognized, however, that specific causation opinions are inadmissible where, as here, the expert eschews the work of ruling out alternative causes by concluding in summary fashion that all potential causes could have contributed to the plaintiff’s disease. *See, e.g., Guerrero v. BP Expl. & Prod. Inc.*, No. 20-0263, 2024 WL 1244796, at *9 (M.D. Fla. Mar. 20, 2024) (excluding specific causation opinion as unreliable because expert failed to “demonstrate serious consideration of [the plaintiff’s] risk factors or how much weight to assign their contributory cause”); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 185 F. Supp. 3d 786, 799 (D.S.C. 2016) (noting that a specific causation expert “cannot simply opine that all present risk factors are ‘substantial contributing factors’”); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 892 F.3d 624, 644 (4th Cir. 2018) (“That Lipitor may cause an increased risk of diabetes notwithstanding certain other risk factors is insufficient to conclude that the drug was a substantial contributing factor in an individual patient. To hold otherwise *would obviate the need for any*

⁴³ (9/13/21 Wolf Dep. 324:8-11, 325:18-24; 9/14/21 Wolf Dep. 533:11-19.)

specific causation evidence at all.”) (emphasis added); *Cano v. Everest Minerals Corp.*, 362 F. Supp. 2d 814, 846 (W.D. Tex. 2005) (rejecting expert methodology that “involves taking a diagnosed condition—cancer—finding all the possible causes of that person’s cancer from the universe of potential causes, and declaring all possible causes to be actual causes and but-for causes”). As the Eleventh Circuit has explained, causation experts “cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development” because a finding that “all possible causes are causes” does not have “general acceptance in the medical and scientific communities.” *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1255 (11th Cir. 2010) (per curiam) (noting that, even where “multiple factors can work together to cause” a disease, an expert is “still required to provide some analysis of why she concluded that, more likely than not, [the agent at issue] substantially contributed to” the occurrence of disease more than other risk factors).

Dr. Wolf’s opinions should be excluded for the same reasons. As recently as 2021, Dr. Wolf conceded that ovarian cancer is “multifactorial,” meaning that all of a patient’s risk factors “could be a cause” of the patient’s cancer.⁴⁴ But Dr. Wolf fails to “assess percentage of cause from different individual risk factors.”⁴⁵

⁴⁴ (9/14/21 Wolf Dep. 523:17-19, 533:11-19.)

⁴⁵ (*Id.* 527:18-21.)

In addition, Dr. Wolf does not believe she can “apportion out or say to what percent any one risk factor may have been a cause.”⁴⁶ Thus, Dr. Wolf fails to provide any “analysis of why she concluded that, more likely than not,” any plaintiff’s talc use—as opposed to all of her other risk factors—caused her ovarian cancer, rendering her opinions inherently unreliable. *See Guinn*, 602 F.3d at 1250, 1255.

A proper differential diagnosis would have required ruling out each plaintiff’s particular risk factors, which—as explained below—include Ms. Bondurant’s endometriosis, Ms. Bondurant and Ms. Judkins’ extensive family histories of cancer, Ms. Gallardo’s post-menopausal hormone replacement therapy, all three plaintiffs’ advanced age, and the distinct possibility that each plaintiff’s cancer has no known cause (i.e., is “idiopathic”).

1. Dr. Wolf Failed To Reliably “Rule Out” Other Potential Causes Of Ms. Bondurant’s Ovarian Cancer.

To conduct a reliable differential diagnosis, an expert must “articulate a reasonable scientific basis for ruling out . . . alternative causes of plaintiff’s” injury. *Soldo*, 244 F. Supp. 2d at 518. Ms. Bondurant had a number of known risk factors for ovarian cancer that Dr. Wolf did not rule out as a cause of her clear cell carcinoma.

⁴⁶ (9/13/21 Wolf Dep. 398:14-19.)

First, Dr. Wolf failed to rule out Ms. Bondurant's [REDACTED], which is a “significant” risk factor for clear cell carcinoma, as a cause of her cancer.⁴⁷ This alone renders her opinions unreliable, because endometriosis has a very strong association with clear cell carcinoma. Indeed, a population-based study of women with surgically verified endometriosis found that this condition was strongly associated with clear cell ovarian cancer, reporting an odds ratio of 10.1 (CI = 5.50-16.9).⁴⁸ In other words, endometriosis, on its own, has been found to be associated with up to a **900%** increased risk of clear cell carcinoma of the ovary. And another study published just this month reported an even higher odds ratio of 11.15 (CI = 6.19-20.10) between endometriosis and clear cell ovarian cancer relative to women without endometriosis.⁴⁹ Dr. Wolf did not contest this association. Instead, she agreed that if Ms. Bondurant “did have [REDACTED],” that would be a risk factor for her cancer.⁵⁰

According to her testimony, Dr. Wolf disregarded this likely alternative cause even though Ms. Bondurant's physician, Dr. Gardner, diagnosed her with [REDACTED] in 1980, and Ms. Bondurant subsequently reported her history of

⁴⁷ (Bondurant Rep. at 23.)

⁴⁸ Saavalainen 2018 at 1095; *see also* Noli 2013.

⁴⁹ Barnard 2024 at E3 tbl. 2.

⁵⁰ (9/14/21 Wolf Dep. 438:14-17; *see also id.* 462:6-7 (“Endometriosis is a risk factor for ovarian cancer.”); *id.* 469:14-25, 476:2-7.)

██████████ to her gynecologic oncologist, Dr. Shank, because Dr. Wolf did not “have a confirmation of it.”⁵¹ This was unreliable and result-oriented. Dr. Wolf readily admitted that she relies on her patients “to give [her] their medical history when they come to see [her].”⁵² Moreover, her methodology is internally inconsistent: conveniently, Dr. Wolf assumes that women are “telling the truth” when they *report using talcum powder in connection with litigation* without any “confirmation,”⁵³ but assumes that Ms. Bondurant was lying in reporting her medical history to her own oncologist.

Second, Dr. Wolf expressly admits that Ms. Bondurant has several other known risk factors for ovarian cancer—including her ██████████ and age of 59 at the time of diagnosis. In fact, Dr. Wolf concedes that Ms. Bondurant’s ██████████ is associated with an odds ratio of 2.0, meaning it *doubles* her risk of ovarian cancer.⁵⁴ By contrast, as noted in Section I, above, the only study reporting an association between talc and clear cell carcinoma reports an odds ratio of only 1.24. Thus, as illustrated below, the

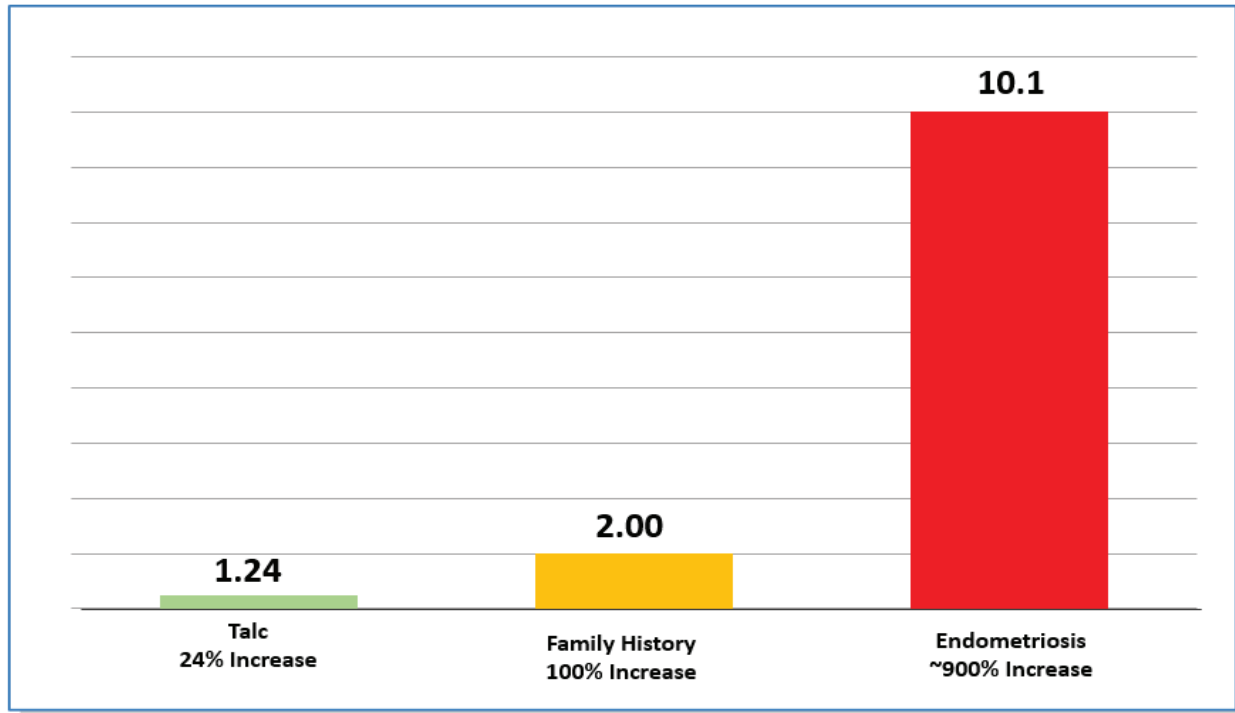
⁵¹ (Id. 463:22-464:12.)

⁵² (Id. 468:12-14.)

⁵³ (Id. 553:10-21.)

⁵⁴ (Bondurant Rep. at 25 (“[H]er family history by itself does increase her risk of ovarian cancer up to 2 times”).)

highest possible increased risk associated with talc exposure is dwarfed by the increase risks associated with Ms. Bondurant's [REDACTED]



In addition, Dr. Wolf also concedes that Ms. Bondurant's age at the time of diagnosis was a potential cause of her cancer because advancing "[a]ge increases anyone's risk for mutations."⁵⁵

Dr. Wolf makes no attempt to rule out any of these risk factors and even admits that some were "cause[s]" of Ms. Bondurant's cancer.⁵⁶ But, as explained

⁵⁵ (9/14/21 Wolf Dep. 577:14-25; *id.* 577:14-15 ("Advancing age can always be a risk factor").)

⁵⁶ (*Id.* 533:11-19 (opining that Ms. Bondurant's [REDACTED] was a "cause" of her ovarian cancer); *id.* 532:17-22 ("[REDACTED] could indicate that there's some genetic underlying hit"); Dep. of Judith Wolf ("4/25/24 Wolf Dep.") 31:8-13, Apr. 25, 2024 (Ex. 17 to Davidson Decl.) (opining that an "inherited gene mutation
(cont'd)

above, Dr. Wolf's opinion that all of Ms. Bondurant's risk factors worked together is not a reliable basis for a specific causation opinion. For this reason, too, her purported differential diagnosis fails.

2. Dr. Wolf Failed To Reliably "Rule Out" Other Potential Causes Of Ms. Judkins' Ovarian Cancer.

Dr. Wolf's opinions as to Ms. Judkins are similarly inadmissible because she failed to "rule out" Ms. Judkins' other potential risk factors for ovarian cancer.

See, e.g., Storey v. Transformhealthrx, Inc., No. 415-149, 2024 WL 695410, at *7 (S.D. Ga. Feb. 20, 2024) (specific causation opinions excluded where expert failed to "rule[] out other potential causes to reach her conclusion that" the defendant's conduct caused the injuries alleged). As with Ms. Bondurant, Dr. Wolf expressly admits that Ms. Judkins has several known risk factors for ovarian cancer that are unrelated to talc—including her [REDACTED] and age of 60 at the time of diagnosis.⁵⁷ Yet once again, she made no effort to explain "why she concluded that, more likely than not," that Ms. Judkins' talc use—as opposed to her [REDACTED] [REDACTED] or age—caused her ovarian cancer. *Guinn*, 602 F.3d at 1250, 1255.

related to ovarian cancer risk" could be a "reason for [Ms. Bondurant's] increased family risk").)

⁵⁷ (9/14/21 Wolf Dep. 579:2-7; *id.* 577:14-15 ("Advancing age can always be a risk factor"); *id.* 578:6-10 ("[A]nyone who's lived to 60 years has had some mutations").)

Dr. Wolf's specific causation opinion with respect to Ms. Judkins is also unreliable because she did not account for the fact that most ovarian cancer is idiopathic. As numerous courts have recognized, failure to evaluate the possibility that unknown causes are to blame for a plaintiff's injuries renders a specific causation analysis unreliable. *See, e.g., Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1311 (11th Cir. 2014) (expert "omitted consideration of idiopathic causes for" the plaintiff's injury, "rendering his differential diagnosis unreliable"); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 675 (6th Cir. 2010) (expert opinion speculative where expert did not consider idiopathic causes, especially because "unknown (idiopathic) causation . . . currently accounts for the vast majority of Parkinson's Disease cases, making it impossible to ignore and difficult to rule out"). Indeed, as the U.S. Court of Appeals for the Eighth Circuit has explained, "[w]here the cause of the condition is unknown in the majority of cases, [an expert] cannot properly conclude, based upon a differential diagnosis," that the plaintiff's exposure to the substance was "the most probable cause" of her injury. *See Bland v. Verizon Wireless (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008).

Dr. Wolf admits that "[i]n many cases, we don't know where" genetic mutations causing ovarian cancer "came from."⁵⁸ She also agrees that it is possible

⁵⁸ (*Id.* 517:4-14.)

Ms. Judkins’ ovarian cancer had “unknown causes.”⁵⁹ Nonetheless, she seeks to opine that the cause of Ms. Judkins’ cancer is talcum powder use.⁶⁰ But simply asserting that talc is a possible cause of cancer is insufficient to rule out the possibility that Ms. Judkins’ cancer was entirely idiopathic. *See Hall v. Conoco Inc.*, 886 F.3d 1308, 1315 (10th Cir. 2018) (upholding exclusion of expert whose “failure to rule out idiopathic causes” of the plaintiff’s acute myeloid leukemia was “a fatal error tainting the differential diagnosis”); *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 476 (1st Cir. 2016) (upholding exclusion of expert testimony based on a differential diagnosis, reasoning that it was unreliable to link benzene to acute promyelocytic leukemia in part because the disease has an extraordinary number of idiopathic cases). Dr. Wolf’s specific causation opinions are also barred for this reason. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1343 (11th Cir. 2010) (expert “failed to apply the differential diagnosis methodology reliably” where he did not explain why idiopathic causes of disease could be ruled out). For this reason, too, her opinions should be excluded.

⁵⁹ (*Id.* 588:1-10.)

⁶⁰ (*Id.*)

3. Dr. Wolf Failed To Reliably “Rule Out” Other Potential Causes Of Ms. Gallardo’s Ovarian Cancer.

Dr. Wolf also fails to reliably “rule out” other potential causes of Ms. Gallardo’s endometrioid cancer—including her age and use of [REDACTED] [REDACTED]—and the possibility that Ms. Gallardo’s cancer is idiopathic.

Dr. Wolf properly identified the fact that Ms. Gallardo underwent [REDACTED] [REDACTED] as a risk factor for her ovarian cancer.⁶¹ Hormone therapy is associated with an increased risk for ovarian cancer overall and endometrioid cancer in particular.⁶² While Dr. Wolf discounted Ms. Gallardo’s [REDACTED] as a potential cause because it lasted for less than a year, she provided no scientific basis for this approach.⁶³ And far from ruling out Ms. Gallardo’s age, Dr. Wolf testified that it was *a* “cause” of her ovarian cancer.⁶⁴ As Dr. Wolf explained, “age is a risk factor, and age increases mutations, so—and the older that women get, the more likely they are to get ovarian cancer.”⁶⁵ Further, Dr. Wolf made no effort to address, much less rule out, the possibility that

⁶¹ (Gallardo Rep. at 24.)

⁶² Liu, *Menopausal Hormone Replacement Therapy and the Risk of Ovarian Cancer: A Meta-Analysis*, 10(801) *Front. Endocrinol.* 1 (2019) (Ex. 18 to Davidson Decl.).

⁶³ (9/13/21 Wolf Dep. 327:7-25.)

⁶⁴ (*Id.* 325:18-24.)

⁶⁵ (*Id.* 266:2-11.)

Ms. Gallardo's cancer was idiopathic. *See, e.g., Milward*, 820 F.3d at 476. For all of these reasons, Dr. Wolf did not conduct a proper differential diagnosis as to Ms. Gallardo.

C. Dr. Godleski's Findings Provide No Support For Dr. Wolf's Specific Causation Opinions.

Finally, Dr. Wolf cannot salvage her opinions by referring to the fact that another plaintiffs' expert, Dr. Godleski, purports to have found particles consistent with talc in subjectively-selected samples of Ms. Judkins' and Ms. Gallardo's pelvic tissue.⁶⁶ For one thing, Dr. Wolf admits that she did not actually rely on these findings in order to reach her opinions because Dr. Godleski "only gets a small portion of the tissue to evaluate."⁶⁷

Moreover, there is no reliable scientific evidence to support a conclusion that the mere presence of alleged talc particles in an ovarian cancer patient's tissue is evidence that the cancer was caused by talc. Indeed, Dr. Godleski himself co-authored a paper in which he expressly *disclaimed* any suggestion that the presence of talc in the body is enough to establish "a causal relationship between

⁶⁶ Dr. Wolf did not reference any pathology findings by Dr. Godleski with respect to Ms. Bondurant. (Bondurant Rep. at 25 ("The presence of talc particles or fibers in a pathology is not a requirement but if present, lends support for causation. I understand that the analysis of Ms. Bondurant's pathology is pending."); 9/14/21 Wolf Dep. 514:24-515:9.)

⁶⁷ (9/14/21 Wolf Dep. 594:16-595:2.)

ovarian cancer and talc use.”⁶⁸ See *In re Mirena Ius Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 341 F. Supp. 3d 213 (S.D.N.Y. 2018), *aff’d*, 982 F.3d 113 (2d Cir. 2020) (“[W]hen an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study.”) (quoting *In re Accutane Prods. Liab.*, No. 04-2523, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), *aff’d*, 378 F. App’x 929 (11th Cir. 2010)). Other published literature is in agreement, including a study noting that talc particles were observed in the ovaries “to a similar extent” with “both ‘exposed and unexposed’ subjects,” none of whom had ovarian cancer.⁶⁹ As a result, Dr. Godleski’s findings cannot provide support for Dr. Wolf’s inherently flawed opinions that talc caused the relevant plaintiffs’ ovarian cancers.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court exclude Dr. Wolf’s specific causation opinions with respect to Ms. Bondurant, Ms. Judkins, and Ms. Gallardo.

⁶⁸ (See Defs.’ Mem. in Supp. of Mot. to Exclude Ops. of Dr. John Godleski at 12 (quoting Cramer, *Presence of Talc in Pelvic Lymph Nodes of a Woman With Ovarian Cancer and Long-Term Genital Exposure to Cosmetic Talc*, 110(2) Obstet. & Gynecol. 498, 500 (2007) (Ex. 19 to Davidson Decl.)).)

⁶⁹ (See *id.* at 19 (quoting Heller, *The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden*, 174(5) Am. J. Obstet. Gynecol. 1507, 1508 (1996) (Ex. 20 to Davidson Decl.)).)

Dated: July 23, 2024

Respectfully submitted,

/s/ Susan M. Sharko

Susan M. Sharko

**FAEGRE DRINKER BIDDLE &
REATH LLP**

Allison M. Brown

Jessica Davidson

**SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP**

*Attorneys for Defendants Johnson &
Johnson and LLT Management, LLC*